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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,874	11/09/2001	John C.K. Hui	4857-00001/CPG	6093

27572 7590 12/17/2003

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EXAMINER	
THANH, QUANG D	

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 12/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,874	HUI, JOHN C.K.	
	Examiner	Art Unit	
	Quang D. Thanh	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-14,16,18-25 and 27-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-14,18-25 and 27-42* is/are rejected.

7)☒ Claim(s) *18,21-26 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 09/24/2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent No. 6,589,267 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

2. Claims 21-26 are objected to because the limitations " The computer-implemented system" recited in these claims lack antecedent basis.

3. Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 18 is objected to because the limitations " inflatable device" and "fluid distribution assembly" have been already recited in claim 10.

4. Claim 31 is objected to because the limitation "deflation" (in line 3 "a leading edge... corresponding to the initiation of deflation") should be – inflation --.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-7, 9-14, 16, 18-25, 27-30, and 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng et al. (5,997,540) in view of Shabty et al. (6,450,981 B1) and Stark et al. (6,371,123).

6. Re claims 1, 10, and 19-20, Zheng et al. discloses a counterpulsation system (fig. 1) comprising: a counterpulsation device having a plurality of inflatable devices 25, a source of compressed fluid 20, a fluid distribution assembly 21/22/24 (fig. 1); a local computer 7 in communication with the fluid distribution assembly of the counterpulsation device to obtain data for controlling the operation of the counterpulsation device (col. 11, lines 7-19), except it is silent regarding a data structure for receiving/storing treatment patient information and a remote computing device to receive the patient information over a communication link . However, Shabty teaches a counterpulsation system (fig. 1) comprising a counterpulsation device having a plurality of inflatable devices 22/24/26 (fig. 1); a data structure 126 for storing treatment patient information for one or more patients (col. 2, lines 26-30 and col. 9, lines 44-48); a computer 10 connected to the counterpulsation device for controlling the operation of the counterpulsation device through each inflation/deflation cycle (col. 9, lines 58-62) and also for receiving the treatment information (col. 9, lines 6-62). Additionally, Stark

teaches a medical device comprising a local handheld computer 20 having a data structure that can store the patient monitoring results (step 3 in fig. 1, col. 7, lines 15-18), which then communicates with another remote central computer 16 over the telephone line through modem connections (Internet) for further processing of the patient data (step 5 in fig. 1, col. 7, lines 32-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify Zheng's system, to have the computer included a data structure to store treatment patient information for one or more patients, as suggested and taught by Shabty et al. and Stark et al., for the purpose of providing and updating a patient profile database that can be used to determine the effectiveness of a counterpulsation therapy regime for an individual patient or selected study groups (Shabty, col. 10, lines 1-4), and to have the system included another remote central computer, as suggested and taught by Stark et al., for the purpose of communicating patient information over the Internet in order to allow review by a treatment professional or to allow updating patient database (Stark, col. 7, lines 50-66).

7. Re claims 2-7, 11-14, 16, 21-25, 28-30 and 36, Shabty further discloses that the data structure is for storing demographic information including patient ID, name and medical data and for storing treatment information including ECG (EKG), blood pressure, heart rate (col. 6, line 60 to col. 7, line 45), and inflation/deflation timing data (col. 7, lines 33-37).

8. Re claims 9 and 18, Zheng further teaches that the computer controls the inflation and deflation of the inflatable devices (col. 11, lines 7-19).

9. Re claim 27, Shabty discloses a counterpulsation system (fig. 1) comprising: a counterpulsation device having a plurality of inflatable devices 22/24/26 and inflation/deflation valve 18 (fig. 1); a data structure 126 for storing treatment patient information for one or more patients (col. 2, lines 26-30 and col. 9, lines 44-48); a computer 10 connected to the counterpulsation device for controlling the operation of the counterpulsation device through each inflation/deflation cycle (col. 9, lines 58-62), for receiving the treatment information (col. 9, lines 6-62), and outputting the operation information; and an output device (display screen) connected to the local computer for displaying treatment and operation information (col. 6, lines 11-20) .

10. Re claims 37-42, Stark teaches that the remote central computer having a database 26 is a medical registry computer (col. 8, lines 33-58), is a computer operable for remote diagnosis (col. 9, lines 16-21), and is a computer operable for training (col. 7, line 66 to col.8, lines 3).

11. Claims 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng/ Shabty/Stark in and further in view of Dillon (5,514,079).

12. Zheng/ Shabty/Stark discloses a counterpulsation system having all the claimed features except that it does not explicitly reveal timing bar having leading edge corresponding to the initiation of inflation and trailing edge corresponding to the initiation of deflation, trigger signal, timing marker with high frequency noise superimposed on an ECG in relation to QRS wave. However, Zheng discloses a counterpulsation system

having a computer that display the wave form, detects the QRS wave of the ECG, performs adaptive processing of the impedance blood flow signals, measures the waveform's characteristic points and controls the inflation and deflation time of the counterpulsation apparatus (col. 11, lines 11-19). Additionally, Shabty teaches that the counterpulsation therapy is carried out by timing the inflation and deflation of the treatment cuffs with certain characteristics of the patient's EKG signal and the plethysmographic blood pressure wave (col. 7, lines 33-36), and those skilled in the medical therapy art will be able to determining the timing of the inflation and deflation of the treatment cuffs and the coordination of that with the patient's natural blood flow in order to provide the desired therapy effect (col. 8, lines 56-60). Moreover, Dillon teaches that, in order to regulate the timing of compression and decompression such that compression and decompression of a patient's leg is phased to the patient's heart beat, one would need EKG sensing device for monitoring the patient's heartbeat, a computer and a timer (col. 6, lines 12-19). Dillon also teaches that compression and decompression of the patient's leg is regulated by sensing the QRS complex in the heart cycle, computing an average time period between a selected number of successive QRS complexes, and initiating a timing cycle for the therapy (col. 4, lines 30-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the system in the combined reference, as suggested and taught by Zheng, Shabty and Dillon, to include means for measuring inflation and deflation time of the counterpulsation apparatus including timing bar having leading edge corresponding to the initiation of inflation and trailing edge corresponding to the

initiation of deflation, trigger signal, timing marker with high frequency noise superimposed on an ECG in relation to QRS wave, for the purpose of determining the timing of the inflation and deflation of the treatment cuffs and regulating the timing of compression and decompression such that compression and decompression of a patient's extremity is in coordination of that with the patient's natural blood flow in order to provide the desired therapy effect (Shabty, col. 8, lines 56-60).

Response to Arguments

13. Applicant's arguments with respect to claims 1-7, 9-14, 16, 18-25, 27- 42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday-Thursday & alternate Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703) 308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Quang D. Thanh
Patent Examiner
Art Unit 3764
December 8, 2003

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
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QT